PATENT
Customer No. 22,852
Attorney Docket No. 06530.0318

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	
John A. GRIEGO et al.	
Application No.: 10/727,626	Group Art Unit: 3739
Filed: December 5, 2003	Examiner: M. J. Kasztejna
For: MEDICAL DEVICE WITH DEFLECTING SHAFT AND RELATED METHODS OF MANUFACTURE AND USE	Confirmation No.: 9106

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

REQUEST FOR CORRECTED PATENT APPLICATION PUBLICATION UNDER 37 C.F.R. § 1.221(b)

The Office published the above-identified application, as Publication No. US 2005-0124912-A1, with a publication date of June 9, 2005. The published application contains a material mistake that is the fault of the Office. Attached hereto is a copy of the relevant pages of the originally filed application (pages 19-22) and a marked-up copy of the corresponding pages of the published application containing the mistake (pages 5 and 6).

The mistake, which is indicated in red ink on the relevant pages of the marked-up copy of the published application attached hereto, is as follows:

- In paragraph [0062], line 6, after "sleeve **75** may be coated," insert text from paragraph [0065], line 3 (after "assembly 60 may"), through paragraph [0068], line 6 (before "include two").

This mistake may create ambiguities, affecting the public's ability to appreciate the technical disclosure of the application publication or to determine the scope of the provisional rights that Applicants may later seek to enforce. See 37 C.F.R. § 1.221(b). For at least this reason, Applicants request that the Office correct the above-identified mistake in the published application.

Applicant believes that no fee is due in connection with this Request. If, however, any Petition or fee is due, please grant the Petition and charge the fee to our Deposit Account no. 06-0916.

Respectfully submitted,

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Dated: July 12, 2005

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locked in place by a suitable mechanism. For example, the bore 69a may have a stepped configuration with varying diameter, where a locking coil may be disposed against a larger diameter area and threadedly engage with the wire coil 45 to secure the wire coil 45 to the handle assembly 60.

[0059] As also shown in Fig. 1, the device 10 includes a control member 70, such as, for example, a single-filament or multi-filament shaft or wire, used for manipulating the end effector assembly 20 from the handle assembly 60. The control member 70 may be flexible enough to pass through a tortuous body cavity, yet sufficiently stiff to resist minor compressive force, thereby permitting axial movement of the control member 70 relative to the control shaft 40. To aid this purpose, the device 10 may optionally include an inner sleeve 75 (see Fig. 3), such as, for example, FEP sheath, extending from the distal end of the wire coil 45 therethrough into the distal shaft 69 of the handle assembly 60. Alternatively, or in addition, this inner sleeve 75 may act as a bearing member between the control member 70 and the lumen of the control shaft 40. The sleeve 75 may be formed of a plastic material, such as, for example, PTFE, Nylon, Pebax, PP, or PE. If the control member 70 is formed of multi-filament shafts or wires, each individual shaft or wire may be covered with the sleeve material.

[0060] In an exemplary embodiment, the control member 70 may be made of stainless steel, nickel-titanium alloy, or a combination of the two, but any other suitable material known in the art may also be used. In another exemplary embodiment, at least a portion of the control member 70 or sleeve 75 may be coated

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with a lubricating material, such as, for example, liquid silicon, to facilitate the axial movement of the control member 70.

[0061] As shown in Figs. 3 and 4, the distal end of each control member 70 may connect to the tang 29 of each jaw 22. The distalmost end of the control members 70 may include a first bent portion 78 which may extend through a bore 78a in the tang 29 and a second bent portion 79 which may be rotatably disposed in the recess 29a of the tang 29. The first bent portion 78 may form an approximately 90° bend with respect to the main portion of the control member 70. The control member 70 may have a reflex curve 77, to aid opening of the jaws 22 when the spool 67 is moved distally.

[0062] As shown in Fig. 1, the handle assembly 60 may include a thumb ring 61 fixedly attached to a main body 65, and a spool 67 slidably coupled to the main body 65, for manipulation of the end effector assembly 20. The spool 67 may be reciprocally slidable along the main body 65 so as to move the control member 70 coupled to the spool 67 relative to the control shaft 40. The spool 67 may be configured to rotate with respect to the axis of the main body 65 so as to control the orientation of the end effector assembly 20. As will be described herein, the reciprocal movement of the spool 67 may control the operation of the end effector assembly 20 as well as the deflection of the distal portion of the control shaft 40.

[0063] The handle assembly 60 may include the distal shaft 69, to which the proximal end of the control shaft 40 may be secured via a suitable locking member. Optionally, the distal shaft 69 may include a strain relief sheath (not shown) over the wire coil 45, which may extend slightly distally from the distal end of the distal shaft

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69, in order to limit twist and movement of the wire coil 45 with the bore of the distal shaft 69 while preventing a sharp bend of the wire coil 45 at the distal end of the handle assembly 60.

[0064] As will be described herein, the proximal end of the control member 70, such as, for example, one or more pull wires, may extend through the control shaft 40 and the distal shaft 69, and fixedly secure to the movable spool 67 via a suitable connecting means, such as, for example, a crimp ring or a cross pin. In the embodiment shown in Fig. 1, the end of a cross pin 63 mates with a slot 62 in the spool 67 so as to lock the cross pin 63 therewith. The proximal ends of the pull wires 70 may then be locked into the cross pin 63 by a set screw 64, so that movement of the spool 67 may thereby effectuate movement of the pull wires 70, the distal ends of which are connected to the end effector assembly 20, as shown in Figs. 3 and 4.

[0065] In an application where mono-polar electric current needs to be supplied to the end effector assembly 20, the handle assembly 60 may include a suitable current supplier, such as an active cord connector, that may contact the control member 70. The control member 70 may then act as an electrical conductor to supply the current received from the current supplier to the end effector assembly 20. In an embodiment, the set screw 64 may be replaced by a suitable active cord connector that may contact the control member 70 and supply the electrical current therethrough to the end effector assembly 20.

[0066] In an application that may require bi-polar current, the two control members 70 may be insulated from each other, and the handle assembly 60 may

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include two separate active cord connectors each contacting the respective one of the two control members 70, so that supplied bi-polar current may be applied across the jaws 22 of the end effector assembly 20. As mentioned above, the distal end of each control member 70 may be connected to the tang 29 of each jaw 22 of the end effector assembly 20. Each jaw 22 may then be insulated from each other and the clevis pin 27 by a non-conductive material, so that the applied current may flow only when the jaws 22 are in contact with each other or through a mutually conducting medium.

[0067] With reference to Figs. 6 and 7, a control mechanism that may enable deflection of a distal portion 48 of the control shaft 40 so as to facilitate movement of the end effector assembly 20 will be described, according to an exemplary embodiment of the invention. As shown in Figs. 6 and 7, the distal portion 48 of the control shaft 40 may be configured to exhibit higher flexibility than that of the remaining portion of the control shaft 40. For example, the exemplary control shaft 40 shown in Figs. 6 and 7 may be formed of a wire coil 45, and the distal portion 48 of the wire coil 45 is formed by a wire 58 having a diameter, *d*, that is smaller than a diameter, *D*, of a wire 52 in the remaining portion of the wire coil 45. The inner diameter of the wire coil 45 may remain substantially the same throughout the length of the wire coil 45. In an exemplary embodiment, for example, the distal portion 48 of the wire coil 45 may have an outer diameter of approximately 0.072 inch (= 1.83 mm), an inner diameter of approximately 0.032 inch (= 0.81 mm), and a wire diameter of approximately 0.020 inch (= 0.51 mm), while the remaining portion of the wire coil 45 may have an outer diameter of approximately 0.080 inch (= 2.0 mm), an

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enough to prevent lumen collapse when tension on the control member **70** is generated. For that purpose, the elongated control shaft **40**, as shown in **FIGS. 3 and 4**, may be formed of a wire coil **45**. The wire coil **45** may include a coating of suitable biocompatible material, such as, for example, PTFE, PP, PE, Nylon, Pebax, Polyimide, or any other materials known in the art, on the outer surface of the wire coil **45**. If the wire coil **45** is used in an electro-active device, the coating may also act as an insulator. Alternatively, or in addition, the control shaft **40** may include a tubular sleeve member, made of a plastic material, such as, for example, Teflon, PTFE, or any other suitable material known in the art. The wire coil **45** may also include a radiopague filler, such as, for example, barium sulfate or tantalum, to enhance visualization under fluoroscopy. In addition, the wire coil **45** may include a hydrophilic lubricious material or other suitable lubricating material to reduce friction. The dimensions of the control shaft **40** may vary depending upon the type of the end effector assembly being used and/or the type of procedure being performed. In an exemplary embodiment, the wire coil **45** may have inner and outer diameters of approximately 0.032 inch (=0.81 mm) and 0.080 inch (=2.0 mm), respectively, and a length of approximately 240 cm.

[0059] The distal end portion **49** of the control shaft **40**, as best shown in **FIGS. 3 and 4**, may be flattened for ease of connection between the proximal portion **21** of the clevis member **24** and the distal end of the control shaft **40**. In various exemplary embodiments, the distal end of the shaft **40** may be connected to the clevis member **24**, with or without the flattened distal end portion **49**, via interference-fit, crimping, soldering, welding, fusing, adhesive, or any other suitable connection mechanisms known in the art.

[0060] The proximal end **41** of the control shaft **40** may be fixedly secured to the handle assembly **60** via a suitable connection mechanism known in the art. In the exemplary embodiment shown in **FIG. 1**, the proximal end of the wire coil **45** extends into a bore **69*a*** formed in a distal shaft **69** of the handle assembly **60** and is locked in place by a suitable mechanism. For example, the bore **69*a*** may have a stepped configuration with varying diameter, where a locking coil may be disposed against a larger diameter area and threadedly engage with the wire coil **45** to secure the wire coil **45** to the handle assembly **60**.

[0061] As also shown in **FIG. 1**, the device **10** includes a control member **70**, such as, for example, a single-filament or multi-filament shaft or wire, used for manipulating the end effector assembly **20** from the handle assembly **60**. The control member **70** may be flexible enough to pass through a tortuous body cavity, yet sufficiently stiff to resist minor compressive force, thereby permitting axial movement of the control member **70** relative to the control shaft **40**. To aid this purpose, the device **10** may optionally include an inner sleeve **75** (see **FIG. 3**), such as, for example, FEP sheath, extending from the distal end of the wire coil **45** therethrough into the distal shaft **69** of the handle assembly **60**. Alternatively, or in addition, this inner sleeve **75** may act as a bearing member between the control member **70** and the lumen of the control shaft **40**. The sleeve **75** may be formed of a plastic material, such as, for example, PTFE, Nylon, Pebax, PP, or PE. If the control member **70** is formed of multi-filament shafts or wires, each individual shaft or wire may be covered with the sleeve material.

[0062] In an exemplary embodiment, the control member **70** may be made of stainless steel, nickel-titanium alloy, or a combination of the two, but any other suitable material known in the art may also be used. In another exemplary embodiment, at least a portion of the control member **70** or sleeve **75** may be coated with, in order to limit twist and movement of the wire coil **45** with the bore of the distal shaft **69** while preventing a sharp bend of the wire coil **45** at the distal end of the handle assembly **60**.

[0063] As will be described herein, the proximal end of the control member **70**, such as, for example, one or more pull wires, may extend through the control shaft **40** and the distal shaft **69**, and fixedly secure to the movable spool **67** via a suitable connecting means, such as, for example, a crimp ring or a cross pin. In the embodiment shown in **FIG. 1**, the end of a cross pin **63** mates with a slot **62** in the spool **67** so as to lock the cross pin **63** therewith. The proximal ends of the pull wires **70** may then be locked into the cross pin **63** by a set screw **64**, so that movement of the spool **67** may thereby effectuate movement of the pull wires **70**, the distal ends of which are connected to the end effector assembly **20**, as shown in **FIGS. 3 and 4**.

[0064] In an application where mono-polar electric current needs to be supplied to the end effector assembly **20**, the handle assembly **60** may include a suitable current supplier, such as an active cord connector, that may contact the control member **70**. The control member **70** may then act as an electrical conductor to supply the current received from the current supplier to the end effector assembly **20**. In an embodiment, the set screw **64** may be replaced by a suitable active cord connector that may contact the control member **70** and supply the electrical current therethrough to the end effector assembly **20**.

[0065] In an application that may require bi-polar current, the two control members **70** may be insulated from each other, and the handle assembly **60** may with a lubricating material, such as, for example, liquid silicon, to facilitate the axial movement of the control member **70**.

[0066] As shown in **FIGS. 3 and 4**, the distal end of each control member **70** may connect to the tang **29** of each jaw **22**. The distalmost end of the control members **70** may include a first bent portion **78** which may extend through a bore **78*a*** in the tang **29** and a second bent portion **79** which may be rotatably disposed in the recess **29*a*** of the tang **29**. The first bent portion **78** may form an approximately 90° bend with respect to the main portion of the control member **70**. The control member **70** may have a reflex curve **77**, to aid opening of the jaws **22** when the spool **67** is moved distally.

[0067] As shown in **FIG. 1**, the handle assembly **60** may include a thumb ring **61** fixedly attached to a main body **65**, and a spool **67** slidably coupled to the main body **65**, for manipulation of the end effector assembly **20**. The spool **67** may be reciprocally slidable along the main body **65** so as to move the control member **70** coupled to the spool **67** relative to the control shaft **40**. The spool **67** may be configured to rotate with respect to the axis of the main body **65** so as to control the orientation of the end effector assembly **20**. As will be described herein, the reciprocal movement of the spool **67** may control the operation of the end effector assembly **20** as well as the deflection of the distal portion of the control shaft **40**.

(cont'd)

[0068] The handle assembly **60** may include the distal shaft **69**, to which the proximal end of the control shaft **40** may be secured via a suitable locking member. Optionally, the distal shaft **69** may include a strain relief sheath (not shown) over the wire coil **45**, which may extend slightly distally from the distal end of the distal shaft include two separate active cord connectors each contacting the respective one of the two control members **70**, so that supplied bi-polar current may be applied across the jaws **22** of the end effector assembly **20**. As mentioned above, the distal end of each control member **70** may be connected to the tang **29** of each jaw **22** of the end effector assembly **20**. Each jaw **22** may then be insulated from each other and the clevis pin **27** by a non-conductive material, so that the applied current may flow only when the jaws **22** are in contact with each other or through a mutually conducting medium.

[0069] With reference to **FIGS. 6 and 7**, a control mechanism that may enable deflection of a distal portion **48** of the control shaft **40** so as to facilitate movement of the end effector assembly **20** will be described, according to an exemplary embodiment of the invention. As shown in **FIGS. 6 and 7**, the distal portion **48** of the control shaft **40** may be configured to exhibit higher flexibility than that of the remaining portion of the control shaft **40**. For example, the exemplary control shaft **40** shown in **FIGS. 6 and 7** may be formed of a wire coil **45**, and the distal portion **48** of the wire coil **45** is formed by a wire **58** having a diameter, d, that is smaller than a diameter, D, of a wire **52** in the remaining portion of the wire coil **45**. The inner diameter of the wire coil **45** may remain substantially the same throughout the length of the wire coil **45**. In an exemplary embodiment, for example, the distal portion **48** of the wire coil **45** may have an outer diameter of approximately 0.072 inch (=1.83 mm), an inner diameter of approximately 0.032 inch (=0.81 mm), and a wire diameter of approximately 0.020 inch (=0.51 mm), while the remaining portion of the wire coil **45** may have an outer diameter of approximately 0.080 inch (=2.0 mm), an inner diameter of approximately 0.032 inch (=0.81 mm), and a wire diameter of approximately 0.024 inch (=0.70 mm). It is to be understood that varying the flexibility of the control shaft **40** may be applied to any portion of the control shaft **40**, including the distal portion **48**, as shown in this example.

[0070] As will be described in more detail herein, this enhanced flexibility in the distal portion **48** relative to the remaining portion of the control shaft **40** allows selective deflection of the distal portion **48**, thereby enhancing the movement of the end effector assembly **20**, as shown in **FIG. 7**. For example, the spool **67** of the handle assembly **60** may be advanced distally to fully open the end effector assembly **20**, as shown in **FIG. 15** and to be described in more detail further herein. Upon further advancement of the spool **67** in the distal direction, additional pressure may be exerted on the control member **70**, and the distal portion **48** having the higher flexibility than the remaining portion of the control shaft **40** may begin to deflect, as shown in **FIGS. 7 and 16**. Depending on the desired degree of deflection, a physician operating the device **10** may readily control the deflection by appropriately adjusting the movement of the spool **67**.

[0071] Alternatively or additionally, in accordance with another embodiment of the invention, the flexibility may be adjusted by utilizing a wire material that has different characteristics from the material characteristics of the wire in the remaining portion. These material characteristics include, but are not limited to, tensile strength, shear strength, or ductility, so as to adjust the desired flexibility of the distal portion **48**, with or without altering the wire diameter in the distal portion **48** of the control shaft **40**.

[0072] In still another exemplary embodiment of the invention, the wire coil **45** may be provided with a deflection control member **71**, such as, for example, a flexible shaft or wire, controlling the deflection of the distal portion **48**, together with the control member **70**, as shown in **FIG. 8**. In this exemplary embodiment, the handle assembly **60** may integrally or separately include a suitable deflection controller for the deflection control member **71**. For example, as shown in **FIGS. 1A**, a deflection controller for the deflection control member **71** may be provided as an additional spool **667*b*** integrally formed in a handle assembly **600** together with the spool **667*a*** for controlling the operation of the end effector assembly. By this arrangement, the deflection of the control shaft may be independently operated by the additional spool **667*b***. While **FIG. 10A** shows the additional spool **667*b*** disposed distal to the spool **667*a***, it may also be positioned proximal to the spool **667*a***, as shown in **FIG. 10B**. Alternatively, the spools **667*a*** and **667*b*** may be configured and positioned along the main body of the handle assembly **600"**, as shown in **FIG. 10C**, so that the spools may slide past one another. The spools shown in the **FIG. 10C** embodiment are of a hemispheric shape to permit translation past one another. The handle assemblies **600**, **600'**, **600"** shown in **FIGS. 10A-10C** may include suitable locking and/or stopping mechanisms, such as, for example, a locking slot, a stopper, or any other mechanism known in the art.

[0073] In operation, once the distal portion **48** is deflected, the deflection control member **71** may be used to hold the distal portion **48** in the deflected position by actuating or locking the deflection controller **667*b***. Alternatively, the deflection control member **71** may independently control the deflection of the distal portion **48** by a suitable, separately arranged deflection controller. The deflection control member **71** may then be actuated, independent from the control member **70**, so as to deflect, hold, and/or straighten the distal portion **48** of the control shaft **40**. For this purpose, a distal end of the deflection control member **71** may be connected to a portion of the distal portion **48**. Other operational aspects of these exemplary embodiments may be similar to the exemplary embodiment described with reference to **FIGS. 14-18**.

[0074] In still another exemplary embodiment of the invention, the wire coil **45** may be provided with a jacket **80** covering at least a portion of the outer surface of the wire coil **45** in the region other than the distal portion **48** intended to be deflected, as shown in **FIG. 9**. The jacket may create an additional stiffness in the covered region, rendering the uncovered distal portion **48** relatively more flexible than the covered proximal region. Jacketing the wire coil **45** may also allow the deflection of the distal portion **48** without modifying the coil in the distal portion **48**. In an exemplary embodiment, the jacket may be made of a polymer material, such as, for example, PTFE, PP, PE, Nylon, Pebax, Polyimide, or any other suitable material.

[0075] In another exemplary embodiment, the distal portion **48** of the wire coil **45** may also be provided with another